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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,451	02/05/2002	Ronald Brown Miller	222.1101CON	8520

23280 7590 07/29/2003

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1615	11

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/067,451	Applicant(s) MILLER ET AL.	
	Examiner Lakshmi S Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 11-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of extension of time and response dated 4-21-03 is acknowledged.

The following rejection made in the last action (paper #8) has been maintained:

4. Claim 17 recites the limitation "the weight ratio of hydrophobic fusible material to hydrophilic organic polymeric wicking agent" in lines 1-3. There is insufficient antecedent basis for this limitation in the claim.

5. Claims 1-8 and 11-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 11-22 of U.S. Patent No. 6,399,096. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant solid, oral, controlled relelase formulations are generic to all water-soluble active ingredients, including the specific drugs such as morphine, tramadol etc., of the patented claims. Besides, both sets of claims recite that the drug is dispersed in a matrix, which results in the same in vitro dissolution rates. Accordingly, the species of the patented claims anticipates the claimed genus of the instant application, and therefore, a patent to the genus would necessarily, extend the rights of the species should the genus issue as a patent after the species.

6. Claims 1-8 and 11-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 5,965,163. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant solid, oral, controlled relelase formulations are generic to the particulate solid dosage forms of the patented claims because instant dependent claim recite microparticulates.

Besides, both sets of claims recite the similar of matrix and also morphine as the active agent in the dependent claims. Instant claim 11 recites the product by process claim, which overlaps with the patented product by process claims. Absent any distinction in the active agent or matrix materials, the patented solid dosage form inherently possess the ability to produce the claimed release rates, as tested by the specified method of instant claims. Accordingly, the species of the patented claims anticipates the claimed genus of the instant application, and therefore, a patent to the genus would necessarily, extend the rights of the species should the genus issue as a patent after the species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 8, 11, 12, 14-17 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,828,836 to Elger et al (hereafter Elger).

Instant claim 1 is directed to an oral, a solid, controlled release pharmaceutical formulation comprising an active agent and a matrix in the formulation. Claim 1 recites specific solubility of the active agents and recites specific relelase patterns of the active agent, as tested by Ph. Eur. Basket Method. Claim 1 primarily requires two components an active agent and a matrix. Dependent claim 4 recites that the matrix comprises a mixture of hydrophobic fusible material having a melting point of greater than 40 degrees C and a hydrophilic polymeric fusible

wicking agent. Claim 8 recites a solid controlled release formulation prepared by the recited process steps.

Elger discloses a solid, controlled release pharmaceutical formulation comprising an active agent incorporated in a controlled release matrix comprising a water-soluble polydextrose, for achieving a slow relelase of drug over extended periods of time. (Col. 1). Elger discloses that the matrix also contains at least one digestible C8-C50 substituted or unsubstituted hydrocarbon, especially a C12-C36 fatty alcohol such as polyethylene glycol and optionally contains hydroxyalkyl or carboxyalkylcellulose (col. 2, lines 11-35). The matrix polymer, polydextrose, and polyethylene glycol taught by Elger read on the instant matrix materials. Although Elger does not state the melting point as claimed, the property is inherent to the compounds because instant specification also states polyethylene glycol as the suitable hydrophobic agent having the claimed melting point. Elger also discloses tablets and capsule, as claimed. The teachings of pellets and granules by Elger meet the claimed particulates because the instant claims do not state the particle size. With respect to the limitations regarding specific release rates, dissolution parameters i.e., ratio of Cmax to mean plasma levels, tmax, W50 etc., and the claimed test method, it is examiner's position that because Elger discloses claimed polymers of the matrix and also discloses various active agents (col. 3) that include the water soluble active agents (for example theophylline in col. 8 and pyridoxine hydrochloride in col. 8, both of which are water soluble), the release rates claimed are inherent to the compositions. Applicant's attention is also directed to the enablement rejection under 35 USC 112, first paragraph (above). Elger further discloses that the release of the active agent is achieved for a long time i.e., 8 hours or more (col. 1, lines 7-12) and figure 2 shows that the release is achieved over 15 –20 hours. With respect to

claim 11, the limitation "the dosage form being obtainable by a process comprising:" is an intended use and the process is not a positive limitation. Furthermore, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elger et al (hereafter Elger).

Instant claims recite a specific ratio of hydrophobic fusible agent and the polymer.

Elger, discussed above, fails to teach exactly the same ratios as claimed, 8:1 to 16:1 and instead teaches a ratio of 1:4 to 4:1. However, the examples of solid controlled relelase compositions taught by Elger (in cols. 7 and 8), Elger teaches a higher amount of hydrophobic polyethylene glycol as compared to polydextrose. Further, Elger teaches the above matrix components for the same purpose as claimed. Accordingly, optimizing the amounts of the hydrophobic and hydrophilic agents in the compositions of Elger so as to achieve a sustained release rate of a given active agent would have been obvious for one of an ordinary skill in the art.

Response to Arguments

Applicant's arguments filed 4-21-03 have been fully considered but they are not persuasive.

1. Applicants have not addressed the rejection of claim 17 as lacking antecedent basis. Accordingly, the rejection has been maintained.

2. Applicants stated that the filing of a terminal disclaimer would be considered upon indicating allowable subject matter. Accordingly, the rejection is still maintained.

3. With respect to the rejection of claims1-4, 8, 11, 12, 14-17 and 23-25 as being anticipated by Elger, applicants argue that under the doctrine of inherency, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish inherency of that result or characteristic. Further, applicants argue the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the alleged inherent characteristic necessarily flows from the teaching of prior art. Applicants did not argue with respect to the matrix materials or the capsule, tablet or particulate forms taught by Elger. Applicants' arguments have been considered but found to be non-persuasive because in the instant rejection Elger teaches a matrix and the same hydrophobic materials as claimed. Instant claims do not recite any specific hydrophilic or hydrophobic wicking materials, or a specific drug. The polymers polyethyleneglycol and dextrose of Elger read on the hydrophilic and hydrophobic mixture of instant claims because polyethylene glycol (PEG) is disclosed in the specification. Accordingly, PEG possess the same characteristics in terms of the release of the drug. In response to the enablement rejection, applicants' state that one does not have to exemplify each and every matrix formulation and the disclosure of one embodiment in the

specification allows for permutations thereof. In other words, applicants admit that all fusible hydrophilic and hydrophobic fusible the polymers are expected to behave in the same way with all the water-soluble drugs and thus an enabling disclosure is not required for each and every polymer that falls under the umbrella of the polymers with claimed characteristics. If applicants' arguments were true, then the polymers of Elger also exhibit the same release characteristics, as claimed. Besides, instant claim 1 recites the release characteristics in intended form "as tested", which is not a positive limitation. Therefore, the rejection has been maintained. Applicants have not argued the rejection of claims 5 ad 17 as being obvious over Elger. Accordingly, the rejection has been maintained.

Applicant's arguments that the disclosure of hydromorphone hydrochloride, diamorphorphone hydrochloride, tramadol hydrochloride and dihydrocodeine tartarate are also recited as other water-soluble active agents filed 4-21-03 with respect to the rejection of claims 1-5, 8, 11, 12, 15 and 17 under 35 USC 112, first paragraph on the grounds of lacking written description have been fully considered and are persuasive.

Applicant's arguments that one does not have to exemplify each and every matrix formulation and the disclosure of one embodiment in the specification allows for permutations thereof and that numerous controlled matrix technologies were well within he knowledge of pharmaceutical formulators filed 4-21-03 with respect to the rejection of claims 1-5, 8, 11, 12, 15, 17 and 22-25 under 35 USC 112, first paragraph claims on the grounds of non-enablement have been fully considered and are persuasive.

The rejection of claims 1-5, 8, 11, 12, 15 and 17 as lacking written description and claims 1-5, 8, 11, 12, 15, 17 and 22-25 as non-enabled have been withdrawn.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Lakshmi S Channavajjala
Examiner
Art Unit 1615
July 28, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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